510(k) Premarket Notification Number: k130056
Date of revision: 03/15/2013

APR 1 1 2013

510(k) Summary
TM-Oxi device

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

1. Submitter's Identification:
Manufacturer: L.D TECHNOLOGY
Address:
100 N.Biscayne Blvd, Suite 502
Miami, FL, 33132, USA
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E mail: albert.ldteck@gmail.com

2. Device Name / Classification
Trade name: Patient monitor
Device Name and Model: TM-Oxi
Regulation number: 21CFR 870.2300
Product Code: MWI
Subsequent Product codes: DXN, DQA
Classification: Class II
Classification Name: monitor, physiological, patient

3. Predicate legally marketed devices
- MD2000BVital Sign Monitor K100740.Applicant: Beijing Choice Electronic Technology Co., Ltd. Product Code MWI. Subsequent Product codes: DXN, DQA
- ESO Software K 102442. Applicant: LD Technology LLC .Product code DQA
- ES Complex Software K113264. Applicant: LD Technology LLC. Product Code DXN, DQA, GZO, MNW
- CMS 50E K090671 Applicant: Contec Medical Systems Co., Ltd Product Code DQA
- MD 200A K093013 Applicant: Beijing Choice Electronic Technology Co., Ltd Product Codes DXN

4. Device Description

The TM-Oxi is a programmable electro medical system using one oximeter and one non-invasive blood pressure device (NIBP). The system comprises:

a. Hardware:
- Non- invasive blood pressure, pump and valve boards and connections, tube, bladder and cuff 510k cleared (K093013) not modified.
- USB HUB DC converter with 3 features
  - ✓ Power supply of NIBP board via USB hub connected to USB port of the PC and

microchip converter 5V to 6 V.

- ✓ Power supply of one oximeter 510k cleared (K090671) not modified via USB hub connected to USB port of the PC.
- ✓ Data transmission via USB hub connected to USB port of the PC.

b. Software:
The used software are ESO software 510k K102442 for data analysis and ES Complex software 510k number k 113264 for data management.
The ES Complex software already manages the data from oximeter (ESO) and blood pressure device (Contec 08A K110774).
Therefore the TM-Oxi system will be a combination of the 2 separate devices.

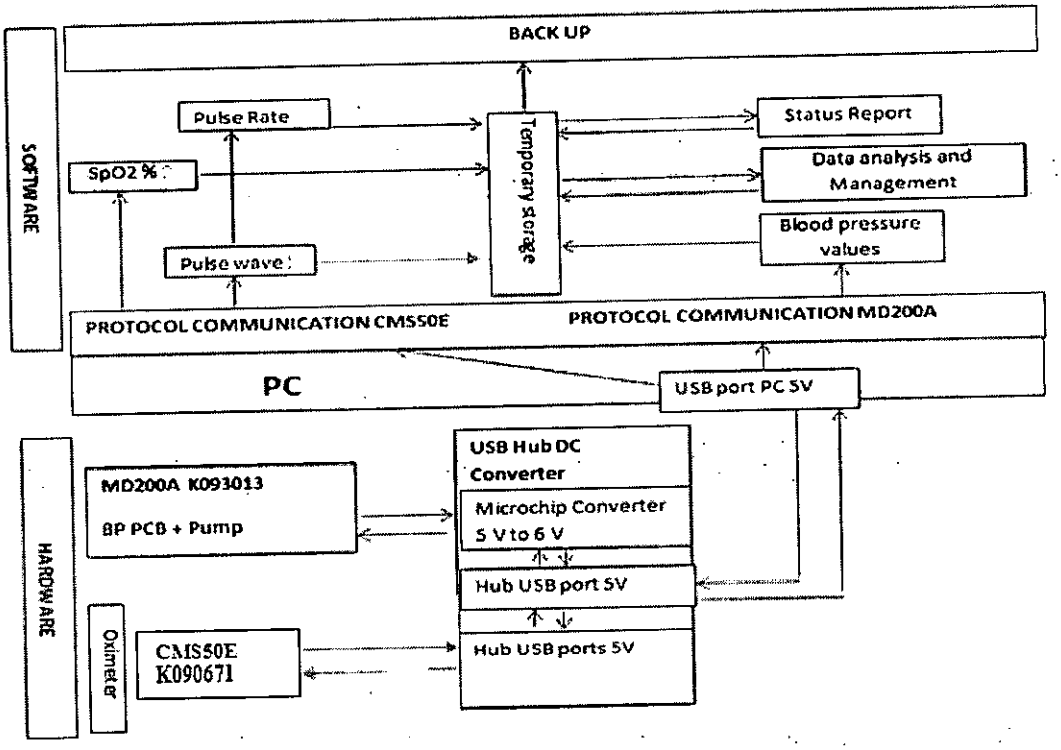
5. Intended use and indications for use

The TM-Oxi device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Non-invasive measurement of blood pressure (NIBP) of adult patients.
The TM-Oxi software uploads the data of the device and displays the data into a computer for enhanced data management. The TM-Oxi software is intended for use in clinical settings as an aid for health care professionals to review, analyze and evaluate the historical tests results.
TheTM-Oxi device is intended for spot-checking of patients.
The TM-Oxi system does not report any diagnosis but provides values. It is the physician's responsibility to make proper judgments based on these numbers.
Prescription Use: Federal law restricts this device to sale by or on the order of a physician.

6. Performances, technical specifications and materials

Performances

Block Diagram TM-Oxi /system



Technical specifications I.e. Device description

Patient contact materials:

The materials in contact with the patient are the cuff, tube, bladder and oximeter probes. Cuff material is nylon and tube and Bladder material are PVC and they are latex free Oximeter probe material is in Thermoplastic polyurethane (TPU) material and latex free.

7. Contra-indications

- **Patients undergoing external defibrillation**
- **Patients connected to electronic life support devices, or any implanted electronic device.**
- Patients moving or long term monitoring
- Do not use this device in the presence of :
  - Magnetic resonance imaging (MR or MRI) equipment. MRI equipment may cause induced current to the device
  - Strong electromagnetic sources, such as electro surgery equipment.
  - Computed tomography (CT) equipment.
- When using the oximeter finger probe, utilize the arm not in use for blood pressure, arterial catheter, or having an AV fistula or pressure dressing.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein
- Significant levels of dysfunctional hemoglogins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO2 measurement.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO2 readings
- Fingernail polish or false fingernails: Fingernail polish or false fingernails may cause inaccurate SpO2 readings
- Venous pulsations may cause erroneous reading in blood pressure (e.g. tricuspid valve regurgitation)
- Caution with low perfused patient. Using the blood pressure device may cause skin erosion and/or pressure necrosis.

8. Undesirable side effects:

Side effects or adverse reactions are none known to date.

9. Substantial equivalence

Predicate legally marketed devices

- MD2000BVital Sign Monitor K100740.Applicant: Beijing Choice Electronic Technology Co., Ltd. Product Code MWI. Subsequent Product codes: DXN, DQA
- ESO Software K 102442. Applicant: LD Technology LLC .Product code DQA
- ES Complex Software K113264. Applicant: LD Technology LLC. Product Code DXN, DQA, GZO, MNW

Similarities

- ✓ The TM-Oxi hardware has same intended use and same performances and effectiveness
- ✓ The TM-Oxi software used the same source codes than ESO and ES Complex software and provides the same analysis and management of the data of the oximeter and blood pressure device.

Hardware Differences:

Hardware Technological characteristics

- ✓ The predicate device has an internal Oximeter PCB board connected to a SpO2 probe. The TM-Oxi uses 510k cleared oximeter which has PCB board and SpO2 probe in one block, USB port, specific USB cable and software provided by the OEM subcontractor.
- ✓ The blood pressure device is powered by the USB port of a PC and microchip converter 5V to 6 V (TM-Oxi) and not AC DC converter, measurements are managed by software and the results are directly display to a PC screen.

Hardware table of comparison

Name device (510k number	TM-Oxi hardware	MD2000B Vital sign monitor K100740
Intended use and features		
Intended use	The TM-Oxi device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Non-invasive measurement of blood pressure (NIBP) of adult patients in medical facilities. TheTM-Oxi device is intended for spot-checking of patients.	The vital signs monitor is a portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Non-invasive measurement of blood pressure (NIBP) of adult and pediatric patients in hospitals, medical facilities, and sub-acute environments. The vital sign monitor is intended for spot-checking and/or continuous monitoring of patients.
SpO2 %	YES	YES
Oximeter Wave form and Pulse rate	YES	YES
Systolic pressure	YES	YES
Diastolic pressure	YES	YES
Output		
Output current	100 mA	75 mA
Output Power	25VA	25VA
Voltage	5V DC	7.2 V DC
Oximeter Technical Specifications		
SpO2% Measuring range	0 to 100%	0 to 100%
SpO2%Accuracy	70%～100%: ±2%, Below 70% unspecified	80-100%:±2%; 70-79%±3%;0-69% Unspecified
Pulse rate measuring range	30 to 250bpm	30 to 235bpm
Pulse rate accuracy	± 2 bpm during the pulse rate range of 30~99 bpm and 2% during the pulse rate range of 100~250 bpm	30-100, ±2bpm; 101-235±2%;0-29 Unspecified
LEDS	Wavelength Red : 660 nm Wavelength IR : 880 nm Radiant Power Red : 1.8 mW Radiant Power IR : 2 mW	Wavelength Red : 660 nm Wavelength IR : 940 nm Radiant Power Red : 1.8 mW Radiant Power IR : 2 mW
BP Technical Specifications		
Measuring principle	Oscillometric	Oscillometric
Measurement mode	Controlled by software	Manual/Automatic/STAT
Measuring range Systolic	30-255 mmHg	30-255 mmHg
Measuring range Diastolic	15-220 mmHg	15-220 mmHg
Other specifications		
Target population	Adult	Adult and pediatric
Application site	Finger	Finger
Display	LCD (oximeter) and PC screen	LCD, LED PC Screen
Power supply	USB	Battery , Converter
Safety Class	BF	BF
Data transmission	USB	USB or flash key (optional)
Testing bench	60601-1-1 60601-1-2 ISO 9919 (from OEM) SP10 (from OEM)	60601-1-1 60601-1-2 ISO 9919 SP10

10. Performances and Effectiveness

1. The OEM subcontractor for MD 200A K093013 provided the PCB boards (blood pressure, pump and valve), tube and bladder, cuff and they were cleared for use together.
2. The OEM subcontractor CMS50 E K090671 provided the oximeter sensor, USB cable connections and software and they were cleared for use together.

Therefore, ISO 9919 report from OEM oximeter and ANSI/AAMI SP10:2002 & ANSI/AAMI SP10:2002/A1:2003/ A2: 2006 report from OEM blood pressure can be used for TM-Oxi

Testing comprises:

1. Integration tests for oximeter and blood pressure device
2. Software structural testing using CRC (Cyclic redundancy check) Coding was performing to demonstrate the software performance to accurately capture, store, and analyze the data measured by the hardware.
3. Laboratory testing for electrical safety (60601-1-1) and EMC (60601-1-2)
4. Software verification (SRS/SDS/STD/STR)

Discussion of requirements of additional Clinical Test

Since the TM-Oxi is using 510K cleared devices clinically tested (ISO 9919 and SP10) and with regard of the testing describe above, the TM-Oxi do not required additional clinical test.

The following facts:

- ✓ The predicate device has an internal Oximeter PCB board connected to a SpO2 probe. The TM-Oxi uses 510k cleared oximeters which have PCB board and SpO2 probe in one block, USB port, specific USB cable and software provided by the OEM subcontractor.
- ✓ The blood pressure device is powered by the USB port of a PC and microchip converter 5V to 6 V (TM-Oxi) and not AC DC converter, measurements are managed by software and the results are directly display to a PC screen.

Do not affect the performances and the effectiveness of the TM-Oxi system as shown in the Integration tests.

11. General Safety Concerns

General Safety Concerns

The laboratory tests reports of the components of TM-Oxi System (IEC 60601-1-2 and IEC 60601-1-1) have demonstrate the general safety of the system comparing to the legally marketed predicate device.

The following facts:

- ✓ The predicate device has an internal Oximeter PCB board connected to a SpO2 probe. The TM-Oxi uses 510k cleared oximeters which have PCB board and SpO2 probe in one block, USB port, specific USB cable and software provided by the OEM subcontractor.
- ✓ The blood pressure device is powered by the USB port of a PC and microchip converter 5V to 6 V (TM-Oxi) and not AC DC converter, measurements are managed by software and the results are directly display to a PC screen.

Do not affect the general safety of the TM-Oxi.

12. Standards

ANSI/AAMI SP10:2002/A1:2003/A2:2006/(R)2008 Issued 2008/12/18.Consolidated version. Manual, Electronic or Automated Sphygmomanometers.
IEC60601-1-1 Issued: 2000/12/14 Ed: 2 Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2 Issued: 2001/09/30 Ed: 2 Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Req. and Tests – Including Section 6 manual review
IEC 60601-2-30: Issued: 1999/12/22 Ed: 2 Medical electrical equipment: Part 2: Particular requirements for the safety, including essential performance, of automatic cycling non- invasive blood pressure monitoring equipment.
Performance testing including clinical and bench testing was conducted to validate and verify that the Blood Pressure Monitor met all design specifications. (OEM subcontractor)
ISO9919 Issued: 2005/03/15 Ed: 2 Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (OEM subcontractor)
Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005
ISO 14971: Medical devices — Application of risk management to medical devices. March 01 2007

Conclusions

TM-Oxi is equivalent in performances, technology, safety and efficacy to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2013

LD Technology, Inc.
c/o Mr. Albert Maarek
Regulatory Consultant
100 North Biscayne Ave, Suite 502
Miami, FL 33132

Re: K130056
Trade/Device Name: TM-Oxi System
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: March 4, 2013
Received: March 5, 2013

Dear Mr. Maarek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130056

Indications for Use

510(k) Number: _____

Device Name: TM-Oxi system

Indications for Use:

The TM-Oxi device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Non-invasive measurement of blood pressure (NIBP) of adult patients.
The TM-Oxi software uploads the data of the device and displays the data into a computer for enhanced data management. The TM-Oxi software is intended for use in clinical settings as an aid for health care professionals to review, analyze and evaluate the historical tests results.
TheTM-Oxi device is intended for spot-checking of patients.
The TM-Oxi system does not report any diagnosis but provides values. It is the physician's responsibility to make proper judgments based on these numbers.
Prescription Use: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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